

Isosorbide Mononitrate 10 mg, 20 mg and 40 mg Tablets

Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET:

1. What Isosorbide Mononitrate is and what it is used for
2. What you need to know before you take Isosorbide Mononitrate
3. How to take Isosorbide Mononitrate
4. Possible side effects
5. How to store Isosorbide Mononitrate
6. Contents of the pack and other information

1 WHAT ISOSORBIDE MONONITRATE IS AND WHAT IT IS USED FOR

- Isosorbide mononitrate belongs to a group of drugs called nitrates. These drugs open out blood vessels and allow more blood to flow through them.
- Isosorbide Mononitrate is used:
 - in the treatment and prevention of angina pectoris attacks which is a chest pain associated with the heart that usually occurs with exertion.
 - in the treatment of heart failure where the heart does not pump with enough force to maintain effective circulation of the blood around the body.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISOSORBIDE MONONITRATE

Do NOT take Isosorbide Mononitrate if you:

- are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients of this medicine
- have ever suffered a reaction to medicines containing nitrates before
- have low blood pressure
- have ever suffered from a heart attack
- have any other problems with your heart or your blood has stopped circulating around your body properly (circulatory failure)
- are suffering from "shock" or vascular collapse
- suffer from glaucoma (loss of vision due to high pressure in the eye)
- have ever suffered a head injury causing pressure in the brain
- have had a brain haemorrhage (bleeding)
- have had a head injury (trauma)
- have a low blood volume (hypovolaemia)
- suffer from severe anaemia which is a reduction in red blood cells
- suffer from galactosaemia which is an inability to digest carbohydrates and sugars found in food and milk products
- take sildenafil, tadalafil and vardenafil or any other phosphodiesterase inhibitor (see taking other medicines)
- have been diagnosed with any of the following heart conditions: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis and diseases associated with raised intra-cranial (head) pressure

Warnings and precautions

Talk to your doctor before taking Isosorbide Mononitrate if you:

- suffer from hypothyroidism (underactive thyroid gland)
- suffer from liver or kidney problems
- are suffering from hypothermia (a body temperature below normal)

- are suffering from malnutrition
- have recently had a heart attack.
- suffer from very poor circulation

Other medicines and Isosorbide Mononitrate

Do NOT take Isosorbide Mononitrate in combination with

- Phosphodiesterase type-5 inhibitors such as sildenafil, tadalafil and vardenafil taken for male erection problems. If this is used by patients taking nitrate preparations such as Isosorbide Mononitrate, a severe and possibly dangerous fall in blood pressure can occur. This would result in collapse and/or unconsciousness and could be fatal.

Talk to your doctor if you are taking any of the following:

- alprostadil (for male erection problems)
- aldesleukin (a cancer treatment)
- candesartan or losartan (for treatment of high blood pressure)
- drugs with blood pressure lowering properties, e.g. beta-blockers (e.g. propranolol), calcium channel blockers (e.g. amlodipine), vasodilators (e.g. hydralazine)
- tricyclic antidepressants (used to treat depression) and neuroleptics (used to treat anxiety).
- ergotamine used for migraine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Isosorbide Mononitrate with food and drink

Do not drink alcohol. It could increase the effect of Isosorbide Mononitrate and lower your blood pressure too much. If this happens, you may feel dizzy or faint.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Isosorbide Mononitrate. Your doctor will decide whether you should take this medicine.

Driving and using machines

Isosorbide Mononitrate may cause headache, blurred vision, dizziness, tiredness, and low blood pressure. If affected do not drive or operate machinery.

Important information about some of the ingredients of Isosorbide Mononitrate

Isosorbide Mononitrate contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 HOW TO TAKE ISOSORBIDE MONONITRATE

Always take Isosorbide Mononitrate exactly as your doctor has told you. Your doctor will tell you how long you should take this medicine to treat your condition. If you are in any doubt, ask your doctor or your pharmacist.

The tablets should be swallowed whole without chewing, preferably with a glass of water after a meal.

The usual dose is:

Adults including the elderly

The recommended dosage is from 20 to 120 mg daily in divided doses.

Most people will require a dosage in the range of 40 to 60 mg daily in divided doses. Your doctor may increase your dose, up to a maximum of 120 mg per day.

Your doctor will tell you when you should take your tablets. You will need to have a period of time (usually when you are sleeping) when no tablets are taken. This is called a "nitrate low" period and is needed to make sure your medicine remains effective. A reduced dose may be given to elderly

patients who are known to be susceptible to the effects of medication that lowers blood pressure.

If you have not taken Isosorbide Mononitrate before, your doctor may tell you to take Isosorbide Mononitrate 10 mg tablets for a few days i.e. 10 mg (1 tablet) daily for 2 days followed by a dosage of 20 mg daily (1 tablet morning and evening) for a further 3 days. Subsequently the daily dose may be increased to the level required to treat your medical condition.

Do not use Isosorbide Mononitrate to treat an actual angina attack. Your doctor will give you a different medicine such as a GTN (glyceryl trinitrate) spray or tablet for this.

Use in children

Isosorbide Mononitrate is not recommended for use in children

If you take more Isosorbide Mononitrate than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause nausea, vomiting, restlessness, warm flushed skin, blurred vision, headache, fainting, dizziness, fast heart rate, low blood pressure, irregular heart beat or confusion. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Isosorbide Mononitrate

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Isosorbide Mononitrate

Do not stop taking your medicine without talking to your doctor first, even if you feel better.

You should not stop taking Isosorbide Mononitrate suddenly. If your doctor decides to stop your treatment, he/she will reduce your dose and how often you take the tablets gradually, and will tell you when you can stop taking them.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Isosorbide Mononitrate can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

Very Common (affecting more than 1 in 10 people):

- Mild headaches at the start of treatment. Usually they disappear after a few days.

Common side effects (affects less than 1 in 10 people):

- Dizziness
- Tiredness
- Feeling weak
- Low blood pressure
- A fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- Fast heartbeat

Uncommon (affects less than one person in 100):

- Fainting or collapse
- Nausea or vomiting
- Skin rash
- Looking pale

- Excessive sweating
- Restlessness
- Slowing of the pulse rate or heart beat
- Worse angina due to very low blood pressure
- Flushing.

Rare (affects less than one person in 1,000):

- Blueness of the face and extremities due to an increase in the amount of methaemoglobin in the blood. Symptoms that you may experience include fatigue, headache or dizziness.

Very rare side effects (affects less than 1 in 10,000 people):

- Heartburn
- Red or scaly skin (exfoliative dermatitis)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE ISOSORBIDE MONONITRATE

Keep this medicine out of the sight and reach of children. Isosorbide Mononitrate should be stored below 25°C. in the original blister package. Do not use this medicine after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What Isosorbide Mononitrate contains:

- The active substance is either 10 mg, 20 mg or 40 mg of isosorbide mononitrate.
- The other ingredients are lactose, microcrystalline cellulose (E460), povidone (E1201), sodium starch glycolate and magnesium stearate (E572).

What Isosorbide Mononitrate tablets look like and contents of the pack:

- Isosorbide mononitrate 10 mg tablets are 'White round bevel edged tablets, engraving 1J1 : plain with breakline
- Isosorbide mononitrate 20 mg tablets are 'White round bevel edged tablets, engraving 1J2 : plain with breakline
- Isosorbide mononitrate tablets 40 mg tablets are 'White round bevel edged tablets, engraving 1J3 : plain with breakline
- Isosorbide Mononitrate 10mg, 20mg, 40mg tablets packs are Blister strips in multiples of 10, 14 or 20 tablets in packs of 10, 14, 28, 30, 50, 56, 60 or 100 tablets. HDPE or polypropylene containers with caps or child resistant closures in packs of 28, 30, 50, 56, 60, 100, 250, 500 or 1000 tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

TEVA Pharmaceutical Works Private Limited Company
Pallagi Street 13, Debrecen, H-4042, Hungary

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